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A 000	INITIAL COMMENTS An unannounced complaint investigation was conducted from 07/31/07-08/02/07 regarding an allegation that the hospital failed to maintain the safety of a patient during restraint. Medical record review of Patient #2 revealed the patient was manually restrained by 7 staff members in the dining room on 02/01/07 at approximately 1210. Record review revealed the patient became unconscious and had no pulse or respirations present at approximately 1215, at which time the manual restraint was released. Record review revealed a Code Blue was called and CPR was initiated at 1215. Record review revealed the patient was transferred to an acute care hospital via EMS at 1235, with resuscitative efforts still in progress, where he was subsequently pronounced dead. The complaint investigation resulted in an immediate jeopardy (IJ) to patients ' health and safety beginning on 02/01/07 at 1210, when the manual restraint occurred. The findings were discussed with the administrative staff on 08/02/07 at 1230. The administrative staff developed and immediately implemented an action plan to correct the deficiencies. The IJ was not removed.	A 000		
A 006	482.12 GOVERNING BODY The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.	A 006		8/10/07

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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A 006	Continued From page 1 This CONDITION is not met as evidenced by: Based on hospital policy and training manual reviews, closed medical record reviews, hospital investigative report review, personnel file reviews and staff interviews the hospital's Governing Body failed to assure effective systems were in place to ensure the safe application of manual restraints of a patient on the floor. The findings include: 1. The hospital failed to have a policy or procedure for the safe and appropriate manual restraint of a patient on the floor. 2. The hospital staff failed to continuously monitor the health status of a patient for 1 of 2 patients in manual restraints reviewed (#2). 3. The hospital failed to implement safe restraint techniques for 1 of 2 patients in manual restraints reviewed (#2). 4. The hospital failed to ensure staff were trained and competent in the application of manual restraints. ~ Cross refer to 482.13 Patient Rights, Tag A0038 5. The hospital failed to ensure a patient was supervised by nursing staff that were trained and competent in the use of restraints, including continuous monitoring of the patient's health status and restraint techniques, for 1 of 2 manually restrained patients reviewed (#2). ~ Cross refer to 482.23 Nursing Services, Tag	A 006		

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A 006	Continued From page 2	A 006		
	A0199			
A 038	482.13 PATIENTS' RIGHTS A hospital must protect and promote the rights of each patient. This CONDITION is not met as evidenced by: Based on hospital policy and training manual reviews, closed medical record reviews, hospital investigative report review, personnel file reviews and staff interviews the hospital failed to protect the rights of a patient in manual restraints on the floor. The findings include: 1. The hospital failed to have a policy or procedure for the safe and appropriate manual restraint of a patient on the floor. ~ Cross refer to 482.13 [e][4][ii] Patient Rights, Tag A0814 2. The hospital staff failed to continuously monitor the health status of a patient for 1 of 2 patients in manual restraints reviewed (#2). ~ Cross refer to 482.13 [e][10] Patient Rights, Tag A0822 3. The hospital failed to implement safe restraint techniques for 1 of 2 patients in manual restraints reviewed (#2). ~ Cross refer to 482.13 [f] Patient Rights, Tag A0835 4. The hospital failed to ensure staff were trained	A 038		8/10/07

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A 038	Continued From page 3 and competent in the application of manual restraints. ~ Cross refer to 482.13 [f][1] Patient Rights, Tag A0837	A 038		
A 199	482.23 NURSING SERVICES The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This CONDITION is not met as evidenced by: Based on hospital policy and training manual reviews, closed medical record reviews, hospital investigative report review, personnel file reviews and staff interviews the hospital failed to provide supervision by a registered nurse trained in the use of manual restraints of a patient lying on the floor for 1 of 2 patients in manual restraints on the floor reviewed (#2). The findings include: The hospital failed to ensure a patient was supervised by nursing staff that were trained and competent in the use of restraints, including continuous monitoring of the patient's health status and restraint techniques, for 1 of 2 manually restrained patients reviewed (#2). ~ Cross refer to 482.23 [b][3] Nursing Services, Tag A0204	A 199		8/10/07
A 204	482.23(b)(3) RN SUPERVISION OF NURSING CARE A registered nurse must supervise and evaluate	A 204		8/10/07

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A 204	Continued From page 4 the nursing care for each patient. This STANDARD is not met as evidenced by: Based on hospital policy and training manual reviews, closed medical record reviews, hospital investigative report review, personnel file reviews and staff interviews the hospital failed to ensure a patient was supervised by nursing staff that were trained in the use of manual restraints of a patient on the floor, including continuous monitoring of the patient's condition, for 1 of 2 manually restrained patients reviewed (#2). The findings include: Review of hospital policy entitled, "Emergency Restrictive Interventions" dated 08/30/06 revealed, "Policy: Isolation time-out, seclusion, manual restraint and/or psychiatric restraint are used only on an emergency basis to terminate a behavior or action in which a patient is in imminent danger of injury to self or others or when substantial property damage is occurring. If possible, verbal or environmental change (i.e. non-physical techniques) is the preferred intervention in the management of behavior. Provision is made for humane, secure, and safe conditions in areas used. Patients are continuously observed during use of all emergency restrictive interventions. Competency-based training and periodic reviews of the use of these procedures are provided to new clinical staff and are conditions of continued employment....Definitions/Guidelines: Emergency Restrictive Interventions: (Note: Any use must be ordered by a physician and reported on the incident report form.)....Manual Restraint (Man. R) The holding of a patient in an emergency for any	A 204		

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length of time in a manner which restricts the patient's freedom of movement. 1. Holding a physically resistive patient in an approved therapeutic hold/carry/walk or other manner that restricts his or her movements constitutes manual restraint for that patient ....This includes therapeutic holds/carries that are approved North Carolina Intervention (NCI) techniques during an emergency, by staff who are NCI-certified. The use of manual restraint for any extended period of time is not sanctioned. 2. When Man. R is utilized, the patient's health status (adequate breathing, signs of physical distress) is assessed during implementation and is documented on the Emergency Restrictive Intervention Progress Note....Implementation of Emergency Restrictive Interventions:...D. RN Responsibility: 1. As soon as notified, conducts a health status assessment which includes:...b. Observing/assessing for respiratory/cardiac distress (clinical assessment of any distress prompts more complete assessment of vital signs)....3. If ERI continues:...b. Assigns a CNA to continuously monitor the patient....h. Documents on the ERI Progress Note:...(5) Health status monitoring for Man. R...." Review revealed no documentation of instructions for the manual restraint of a patient on the floor.

Review of "North Carolina Intervention" manual dated 03/31/03 revealed, "It is important to remember that the immediate goal of the restrictive intervention is to insure the safety of the person and those in the surrounding area. Once the person is restrained, staff involved should insure that the person is safe within the intervention. They are breathing freely, no apparent circulation problems..." Review revealed the NCI program provides instruction in

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the use of non-physical techniques as well as therapeutic holds and transport techniques. Review revealed no documentation of instructions for the manual restraint of a patient on the floor.

Medical record review of Patient #2 revealed the patient was admitted on 01/01/07 for paranoid schizophrenia and died on 02/01/07. Review of the physician's discharge summary dated 02/23/07 revealed, "(Patient's name) was admitted grossly psychotic with a long history of psychiatric care ...The first part of his stay here was characterized by behavioral volatility, including inappropriate and bizarre behavior ...patient was initiated on Zyprexa (an antipsychotic medication) on or about 1/18/07 ...Over the course of the next twelve days, (Patient's name) showed significant improvement. He stopped making so many bizarre statements and became much more engaged with regards to his own personal self-care and personal hygiene. He was still, even on interview, the day before his death, very disorganized and answered many questions with nonsequiturs. However, he was able to sit still, which was markedly improved. He was able to respond at least at times appropriately, which was markedly improved and his hygiene showed gross improvement ....Throughout his stay, (Patient's name) really did not have any great physical complaints ... (Patient's name) became abruptly agitated while in the dining room at lunch (on the date of his death). He appeared to be looking for more food, which he had done before and refused redirection. In the past, he typically was redirectable by at least a few staff members and especially lately, had been more redirectable in general. This time, for reasons still unknown to us, he became intensely irate, intensely agitated,

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and began to throw trashcans around, threatening harm to peers and to staff. Subsequently, he was manually restrained and in the context of that restraint, he apparently suffered some kind of cardiac event and despite provision of CPR on the scene, as well as rapid response of EMS, he expired ..."

Medical record review of documentation by Staff B (a nursing assistant) dated 02/01/07 at 1307 (denoted as "late entry") revealed, "pt. (patient) said 'He was still hungry'; after eating his lunch. Pt was trying to get more food from the ladies that serve food from the window. Pt was redirected, it was effective @ that time. Pt. started going to his table to sit down, he stopped and got five packs of mayo. Pt. said 'I am going to eat them' staff took mayo from the pt.; pt. then walked around, took food out of trashcan and started eating it. Pt. was redirected ineffective staff stopped following pt. Pt. turned trashcan over picked up another trashcan. Mediation was called and ET (Emergency Transmission) button was hit. Staff grabbed pt. then staff lowered pt. to ground pt. tried to kick, bite staff. Pt. was not responding to his name. Staff called 2121 Code Blue other staff got first aid kit such as O2 (oxygen) tank and all for CPR."

Medical record review of documentation by Staff L (a nursing assistant) dated 02/01/07 at 1330 (denoted as "late entry") revealed, "I (name of Staff L) walked in, from lunch @ 1200. Everything was ok as usual a few minutes went by. As pt ...stood up and grabbed 4 pack of mayonnaise I and (Staff B) asked pt to give us the mayo pr would not hand them over so we grabbed his hands and took them away. Pt. got up started digging in the trash for mayo or other

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food. Pt. was very angry. Pt. picked up the trash can and threw it towards staff. A staff member (Staff A), grabbed pt as other staff approached to help. We finally got pt on the ground. Pt. was fighting to get up, pt still angry. After a few minutes pt seemed to have calmed down so we gradually let go but pt wasn't moving or breathing so a staff member called the code while (Staff F) stared CPR. I held the left arm, (Staff I) held right arm, (Staff J) held right leg, (Staff D) held left leg, and (Staff A) on top. (Staff A)'s back facing me could not see pts face or the CNA (nursing assistant) arms or hands."

Medical record review of documentation by Staff J (a nursing assistant) dated 02/01/07 at 1345 (denoted as "late entry") revealed, "...(Staff A) came in and took him down, I seen (Staff A) on top of (Patient's name). I could not see (Patient's name)'s face at all. I did see (Staff I) on (Patient's name)'s right arm holding it. (Staff M) and I were on the right leg. (Staff B) was on the left. (Staff L) had his left arm holding it. (Patient's name) was violently struggling throughout to get up. After several minutes he just stopped. Then a nurse asked someone to call 2121 (Code Blue). The medical team came in. Then I was asked to get up and return to my ward."

Medical record review of documentation by Staff M (a registered nurse, RN) dated 02/01/07 at 1300 (denoted as "late entry") revealed, "..."at approximately 1210 pt threw trash can at staff. Pt was placed in MR (manual restraint) resisting staff, I then assisted (Staff A), (Staff L), (Staff D), (Staff I) and (Staff J) with MR. (Staff J) and I were holding pt's L (left) leg. ET was alerted at approximately 1211. (Staff N) RN arrived. Pt was still combative. Approximately 1212 (Staff C)

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RN and (Staff F) LPN (licensed practical nurse) arrived to assist, at approximately 1215 pt became unresponsive. (Staff N) called code ...."

Medical record review of documentation by Staff I (a nursing assistant) dated 02/01/07 at 1310 (denoted as "late entry") revealed, "...he (Patient #2) grabbed trash can and threw it at staff. At that time we grabbed pt and rolled him to the floor. I had his right arm holding it down, (Staff L) + (Staff D) had his left legg holding it and (Staff J) had his right legg holding it down. (Staff A) was laying across left side of Pt chest with his left arm across his back. We tried letting Pt up to take him to restraint room but Pt start kicking again. Someone asked if we could get an IM (intramuscular injection) and someone said the nurse was bring it. (Staff N) RN said she would give the shot when it came. Shot was not given. Pt went relaxed and (Staff N) said check his eyes and breathing. (Staff C) RN checked and Pt took deep breaths and then stopped. (Staff F) and (Staff C) started CPR and the code team was called ...."

Medical record review of documentation by Staff C (a RN) dated 02/01/07 at 1330 (denoted as "late entry") revealed, "Upon entering the F1 dining room patient in manual restraints, which was 1210. Patient in manual restraints, duration of five minutes from my arrival. Patient not responding to redirection during manual restraint continued fighting and attempting to bite staff member (Staff A) who was straddling patient. (Staff A) was repeatedly asked if he had weight on him in which his reply was 'no I'm not on him'. (Staff N) attempted to reach patient's doctor for possible PRN (as needed medication) order. Patient continued to fight the manual restraint c

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(with) no acute physical distress. (Staff N) arrived back @ manual restraint. This writer was to the side of the patient and (Staff N) @ patient's head. At 1215 patient non responsive to verbal or tactile stimulation. (Staff N) and this writer told (Staff A) to get back from patient. No respirations present or pulse present. Staff member called 2121 @ this writer's request ...."

Review of documentation available in the hospital's investigative report by Staff N (a RN) dated 02/01/07 at 1338 revealed, "1212 I walked into dining room p (after) care team was called. Staff had the pt. in the floor. He was screaming and growling at staff. I walked to the door going to the kitchen and called for the operator to page (Physician's Name) at 1213. I walked back staff had stated that the nurses were out side. I walked to the patient's face and became concerned his eyes were closed and his tounge protruded slightly c (with) blue tint. I note at the same time that (Staff A's name) had his R (right) hand on his (pts.) neck Firmly and took his hand told him not to do that and to 'get off his chest' I said twice. Some staff are saying in the background 'he will start again'. I said no he's not breathing. 2 or 3 of us said call a code ...." Further review of the hospital's investigative report revealed documentation of a second note by Staff N dated 02/01/07 at 1706 (denoted as "late entry"). Review of the second note made by Staff N revealed, "Heard care team (ET response team) called to (F1) dineing room and responded. Upon arrival 2 RN's and CNA's had pt in NCI Hold. RN's stated pt. was too agitated to move out of the dining room. 1213 called hospital operator. Pt. was growling and kicking fighting staff. Requested operator to call (Physician's name) ASAP to (F1) dining room or this phone.

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Walked back to pt. assessed his face eyes were closed and tounge was protruded slightly c (with) blueish tint. Instructed staff to stop NCI. Attempted to obtain response, or pulse, and breath sounds. None noted began CPR ..."

Review of documentation available in the hospital's investigative report by Staff A (a nursing assistant) dated 02/01/07 at 1730 revealed, "... (patient) threw the can. At this point to keep other pts and staff safe I wrapped my arms around him from behind. One arm across his right shoulder the other under his left arm and locked my hands in front. I was unable to get him to the floor so I thought if I just hang on till help comes that will at least slow him down. Staff came from all directions trying to grab body parts arms, legs etc. Someone got hold of his head and started pulling down to get him to go to the floor. When I felt the pt starting to go to the floor I quickly loosened my hold to slide around in front of him because he was going to go down on his back. Still with same hold on the floor pt's right side of face was on my right chest. Pt was fighting very hard and at same time was trying so hard to turn his head and bite me that his eyes turned blood red and looked as if they were going to pop out. Pt was being held by many staff at this point....when pt had a real hard aggressive attempt to get up and to bite Pt looked as if he passed out so we slowly got off him. At this point RN's checking out Pt and had no response and called Code Blue team."

Interview with Staff C on 08/01/07 at 1600 revealed during the manual restraint of Patient #2 on the floor of the dining room on 02/01/07 he and Staff M (the other RN present) "were trying to figure out how to move the patient". Interview

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revealed the usual process would be to hold the patient down just until he either calmed down and could safely be walked to a safe environment, such as a seclusion or restraint room, or to manually carry the patient (if he is still combative) to a seclusion or restraint room. Interview revealed there are seclusion and restraint rooms readily available on the patient wards and in the treatment mall (the day area). Interview revealed there were no seclusion or restraint rooms in the dining room. Interview revealed in order to carry the patient to the closest seclusion or restraint room, which would have been on Ward 6, they would have had to carry him through 3 sets of doors, 2 of which were locked. Interview revealed carrying the patient to Ward 6 was not feasible because of his large size and the amount of force with which he was fighting the staff. Interview revealed another nurse called the physician to get an order for a PRN medication to help calm the patient. Interview revealed the staff continued to manually restrain the patient until he became unresponsive. Interview revealed there was no plan or process in place for the transport of a physically combative patient from the dining room to a seclusion or restraint room.

Nine staff members that witnessed and/or were involved in the manual restraint of Patient #2 in the dining room on 02/01/07 were interviewed on 08/01/07 between 1330 and 1900 (Staff A, Staff B, Staff C, Staff D, Staff E, Staff F, Staff H, Staff I and Staff N). Interview with all 9 staff members revealed the patient was manually restrained on the floor with staff members holding all 4 extremities. All 9 interviews revealed a staff member was positioned on top of the patient diagonally across the patient's chest.

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A 204	Continued From page 13 Nine direct patient care staff members (nurses and nursing assistants) were interviewed on 08/01/07 between 1330 and 1900 (Staff A, Staff B, Staff C, Staff D, Staff F, Staff I, Staff K and Staff N). 8 of the 9 staff members interviewed revealed there was no policy or procedure available at the hospital for the manual restraint of a patient on the floor. All of the staff members interviewed revealed the hospital uses NCI techniques for emergency restrictive interventions. Interviews revealed the NCI techniques do not include the use of manual restraints on a patient after the patient is on the floor. Medical record review revealed no documented evidence of an Emergency Restrictive Intervention (ERI) Progress Note, including health status monitoring, or of a health status assessment (including observations/assessments for respiratory/cardiac distress) by a nurse during the implementation of the manual restraint. Administrative staff interview on 08/02/07 at 0845 revealed there was no policy or procedure available at the hospital for the manual restraint of a patient on the floor. Interview revealed the hospital uses NCI techniques for emergency restrictive interventions. Interview confirmed the NCI techniques do not include the use of manual restraints on a patient after the patient is on the floor. Interview revealed administrative staff had "never thought in terms of we have no practice for this" prior to the incident with Patient #2 on 02/01/07. Interview revealed the process of transporting the patient in his combative state during the manual restraint on 02/01/07 should have been to move him to Ward 6 to a seclusion or restraint room. Interview revealed the staff	A 204		

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A 204	Continued From page 14 involved in the manual restraint "couldn't carry him because of his size and the amount of violence". Interview confirmed there was no plan or process for the transport of a physically combative patient from the dining room to a seclusion or restraint room. Interview confirmed there was no documentation available of a health status assessment (including observations/assessments for respiratory/cardiac distress) by a nurse during the implementation of the manual restraint. Interview also confirmed there was no documentation available of an ERI Progress Note or of health status monitoring for the manual restraint.	A 204		
A 814	482.13(e)(4)(ii) PATIENT RIGHTS: RESTRAINT OR SECLUSION The use of restraint or seclusion must be implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law. This STANDARD is not met as evidenced by: Based on hospital policy and training manual reviews, closed medical record reviews, hospital's investigative report review and staff interviews the hospital failed to have a policy or procedure for the safe and appropriate manual restraint of a patient on the floor. The findings include: Review of hospital policy entitled, "Emergency Restrictive Interventions" dated 08/30/06 revealed, "Policy: Isolation time-out, seclusion, manual restraint and/or psychiatric restraint are used only on an emergency basis to terminate a	A 814		8/10/07

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A 814	Continued From page 15	A 814		

behavior or action in which a patient is in imminent danger of injury to self or others or when substantial property damage is occurring. If possible, verbal or environmental change (i.e. non-physical techniques) is the preferred intervention in the management of behavior. Provision is made for humane, secure, and safe conditions in areas used ....Definitions/Guidelines: Emergency Restrictive Interventions: (Note: Any use must be ordered by a physician and reported on the incident report form.)....Manual Restraint (Man. R) The holding of a patient in an emergency for any length of time in a manner which restricts the patient's freedom of movement. 1. Holding a physically resistive patient in an approved therapeutic hold/carry/walk or other manner that restricts his or her movements constitutes manual restraint for that patient ....This includes therapeutic holds/carries that are approved North Carolina Intervention (NCI) techniques during an emergency, by staff who are NCI-certified. The use of manual restraint for any extended period of time is not sanctioned ..." Review revealed no documentation of instructions for the manual restraint of a patient on the floor.

Review of "North Carolina Intervention" manual dated 03/31/03 revealed, "...the immediate goal of the restrictive intervention is to insure the safety of the person and those in the surrounding area." Review revealed the NCI program provides instruction in the use of non-physical techniques as well as therapeutic holds and transport techniques. Review revealed no documentation of instructions for the manual restraint of a patient on the floor.

Medical record review of Patient #2 revealed the

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patient was admitted on 01/01/07 for paranoid schizophrenia. Record review revealed the patient was manually restrained on the floor of the dining room by 7 staff members on 02/01/07 at approximately 1210. Record review revealed at approximately 1215 it was noted that the patient was not breathing and had no pulse. Record review resuscitative efforts were immediately initiated and the patient was transferred to an acute care hospital at approximately 1235, where he subsequently was pronounced dead.

Nine staff members that witnessed and/or were involved in the manual restraint of Patient #2 in the dining room on 02/01/07 were interviewed on 08/01/07 between 1330 and 1900 (Staff A, Staff B, Staff C, Staff D, Staff E, Staff F, Staff H, Staff I and Staff N). Interview with all 9 staff members revealed the patient was manually restrained on the floor with staff members holding all 4 extremities. All 9 interviews revealed a staff member was positioned on top of the patient diagonally across the patient's chest.

Interview with Staff C (a RN present at the restraint) on 08/01/07 at 1600 revealed during the manual restraint of Patient #2 on the floor of the dining room on 02/01/07 he and Staff M (the other RN present) "were trying to figure out how to move the patient". Interview revealed the usual process would be to hold the patient down just until he either calmed down and could safely be walked to a safe environment, such as a seclusion or restraint room, or to manually carry the patient (if he is still combative) to a seclusion or restraint room. Interview revealed there are seclusion and restraint rooms readily available on the patient wards and in the treatment mall (the day area). Interview revealed there were no

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seclusion or restraint rooms in the dining room. Interview revealed in order to carry the patient to the closest seclusion or restraint room, which would have been on Ward 6, they would have had to carry him through 3 sets of doors, 2 of which were locked. Interview revealed carrying the patient to Ward 6 was not feasible because of his large size and the amount of force with which he was fighting the staff. Interview revealed another nurse called the physician to get an order for a PRN medication to help calm the patient. Interview revealed the staff continued to manually restrain the patient until he became unresponsive. Interview revealed there was no plan or process in place for the transport of a physically combative patient from the dining room to a seclusion or restraint room.

Nine direct patient care staff members (nurses and nursing assistants) were interviewed on 08/01/07 between 1330 and 1900 (Staff A, Staff B, Staff C, Staff D, Staff F, Staff I, Staff K and Staff N). 8 of the 9 staff members interviewed revealed there was no policy or procedure available at the hospital for the manual restraint of a patient on the floor. All of the staff members interviewed revealed the hospital uses NCI techniques for emergency restrictive interventions. Interviews revealed the NCI techniques do not include the use of manual restraints on a patient after the patient is on the floor.

Administrative staff interview on 08/02/07 at 0845 revealed there was no policy or procedure available at the hospital for the manual restraint of a patient on the floor. Interview revealed the hospital uses NCI techniques for emergency restrictive interventions. Interview confirmed the

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A 814	Continued From page 18 NCI techniques do not include the use of manual restraints on a patient after the patient is on the floor. Interview revealed administrative staff had "never thought in terms of we have no practice for this" prior to the incident with Patient #2 on 02/01/07. Interview revealed the process of transporting the patient in his combative state during the manual restraint on 02/01/07 should have been to move him to Ward 6 to a seclusion or restraint room. Interview revealed the staff involved in the manual restraint "couldn't carry him because of his size and the amount of violence". Interview confirmed there was no plan or process for the transport of a physically combative patient from the dining room to a seclusion or restraint room.	A 814		
A 822	482.13(e)(10) PATIENT RIGHTS: RESTRAINT OR SECLUSION The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy. This STANDARD is not met as evidenced by: Based on hospital policy review, closed medical record reviews, hospital's investigative report review, personnel file reviews and staff interviews the hospital staff failed to continuously monitor the health status of a patient for 1 of 2 patients in manual restraints reviewed (#2). The findings include: Review of hospital policy entitled, "Emergency	A 822		8/10/07

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A 822	Continued From page 19 Restrictive Interventions" dated 08/30/06 revealed, "Patients are continuously observed during use of all emergency restrictive interventions. Competency-based training and periodic reviews of the use of these procedures are provided to new clinical staff and are conditions of continued employment....Definitions/Guidelines: Emergency Restrictive Interventions: (Note: Any use must be ordered by a physician and reported on the incident report form.)....Manual Restraint (Man. R) The holding of a patient in an emergency for any length of time in a manner which restricts the patient's freedom of movement. 1. Holding a physically resistive patient in an approved therapeutic hold/carry/walk or other manner that restricts his or her movements constitutes manual restraint for that patient ....This includes therapeutic holds/carries that are approved North Carolina Intervention (NCI) techniques during an emergency, by staff who are NCI-certified. The use of manual restraint for any extended period of time is not sanctioned . 2. When Man. R is utilized, the patient's health status (adequate breathing, signs of physical distress) is assessed during implementation and is documented on the Emergency Restrictive Intervention Progress Note....Implementation of Emergency Restrictive Interventions:...D. RN Responsibility: 1. As soon as notified, conducts a health status assessment which includes:...b. Observing/assessing for respiratory/cardiac distress (clinical assessment of any distress prompts more complete assessment of vital signs)....3. If ERI continues:...b. Assigns a CNA to continuously monitor the patient....h. Documents on the ERI Progress Note:...(5) Health status monitoring for Man. R...."	A 822		

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A 822	Continued From page 20	A 822		

Review of "North Carolina Intervention" manual dated 03/31/03 revealed, "It is important to remember that the immediate goal of the restrictive intervention is to insure the safety of the person and those in the surrounding area. Once the person is restrained, staff involved should insure that the person is safe within the intervention. They are breathing freely, no apparent circulation problems..."

Medical record review of Patient #2 revealed the patient was admitted on 01/01/07 for paranoid schizophrenia and died on 02/01/07. Review of the physician's discharge summary dated 02/23/07 revealed, "(Patient's name) was admitted grossly psychotic with a long history of psychiatric care ...The first part of his stay here was characterized by behavioral volatility, including inappropriate and bizarre behavior ...patient was initiated on Zyprexa (an antipsychotic medication) on or about 1/18/07 ...Over the course of the next twelve days, (Patient's name) showed significant improvement. He stopped making so many bizarre statements and became much more engaged with regards to his own personal self-care and personal hygiene. He was still, even on interview, the day before his death, very disorganized and answered many questions with nonsequiturs. However, he was able to sit still, which was markedly improved. He was able to respond at least at times appropriately, which was markedly improved and his hygiene showed gross improvement ....Throughout his stay, (Patient's name) really did not have any great physical complaints ... (Patient's name) became abruptly agitated while in the dining room at lunch (on the date of his death). He appeared to be looking for more food, which he had done before and refused

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A 822	Continued From page 21	A 822		

redirection. In the past, he typically was redirectable by at least a few staff members and especially lately, had been more redirectable in general. This time, for reasons still unknown to us, he became intensely irate, intensely agitated, and began to throw trashcans around, threatening harm to peers and to staff. Subsequently, he was manually restrained and in the context of that restraint, he apparently suffered some kind of cardiac event and despite provision of CPR on the scene, as well as rapid response of EMS, he expired ..."

Medical record review of documentation by Staff M (a registered nurse, RN) dated 02/01/07 at 1300 (denoted as "late entry") revealed, "..."at approximately 1210 pt threw trash can at staff. Pt was placed in MR (manual restraint) resisting staff, I then assisted (Staff A), (Staff L), (Staff D), (Staff I) and (Staff J) with MR. (Staff J) and I were holding pt's L (left) leg. ET was alerted at approximately 1211. (Staff N) RN arrived. Pt was still combative. Approximately 1212 (Staff C) RN and (Staff F) LPN (licensed practical nurse) arrived to assist, at approximately 1215 pt became unresponsive. (Staff N) called code ...." Review revealed no documentation of a health status assessment, including observations/assessments for respiratory/cardiac distress by Staff M, the first nurse present at the Emergency Restrictive Intervention (manual restraint).

Medical record review of documentation by Staff C (a RN) dated 02/01/07 at 1330 (denoted as "late entry") revealed, "Upon entering the F1 dining room patient in manual restraints, which was 1210. Patient in manual restraints, duration of five minutes from my arrival. Patient not

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responding to redirection during manual restraint continued fighting and attempting to bite staff member (Staff A) who was straddling patient. (Staff A) was repeatedly asked if he had weight on him in which his reply was 'no I'm not on him'. (Staff N) attempted to reach patient's doctor for possible PRN (as needed medication) order. Patient continued to fight the manual restraint c (with) no acute physical distress. (Staff N) arrived back @ manual restraint. This writer was to the side of the patient and (Staff N) @ patient's head. At 1215 patient non responsive to verbal or tactile stimulation. (Staff N) and this writer told (Staff A) to get back from patient. No respirations present or pulse present. Staff member called 2121 @ this writer's request ...." Review revealed no documentation of a health status assessment, including observations/assessments for respiratory/cardiac distress by Staff C during the Emergency Restrictive Intervention (manual restraint).

Medical record review revealed no documented evidence of an Emergency Restrictive Intervention (ERI) Progress Note, including health status monitoring, or of a health status assessment (including observations/assessments for respiratory/cardiac distress) by a nurse during the implementation of the manual restraint.

Administrative staff interview on 08/02/07 at 0845 confirmed there was no documentation available of a health status assessment (including observations/assessments for respiratory/cardiac distress) by a nurse during the implementation of the manual restraint. Interview also confirmed there was no documentation available of an ERI Progress Note or of health status monitoring for the manual restraint.

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A 835	482.13(f) PATIENT RIGHTS: RESTRAINT OR SECLUSION The patient has the right to safe implementation of restraint or seclusion. This STANDARD is not met as evidenced by: Based on hospital policy and training manual reviews, closed medical record reviews, hospital's investigative report review and staff interviews the hospital failed to implement safe restraint techniques for 1 of 2 patients in manual restraints reviewed (#2). The findings include: Review of hospital policy entitled, "Emergency Restrictive Interventions" dated 08/30/06 revealed, "Policy: Isolation time-out, seclusion, manual restraint and/or psychiatric restraint are used only on an emergency basis to terminate a behavior or action in which a patient is in imminent danger of injury to self or others or when substantial property damage is occurring. If possible, verbal or environmental change (i.e. non-physical techniques) is the preferred intervention in the management of behavior. Provision is made for humane, secure, and safe conditions in areas used ....Definitions/Guidelines: Emergency Restrictive Interventions: (Note: Any use must be ordered by a physician and reported on the incident report form.)....Manual Restraint (Man. R) The holding of a patient in an emergency for any length of time in a manner which restricts the patient's freedom of movement. 1. Holding a physically resistive patient in an approved therapeutic hold/carry/walk or other manner that restricts his or her movements constitutes manual restraint for that patient ....This includes therapeutic holds/carries	A 835		8/10/07

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A 835	Continued From page 24	A 835		

that are approved North Carolina Intervention (NCI) techniques during an emergency, by staff who are NCI-certified. The use of manual restraint for any extended period of time is not sanctioned ..." Review revealed no documentation of instructions for the manual restraint of a patient on the floor.

Review of "North Carolina Intervention" manual dated 03/31/03 revealed, "...the immediate goal of the restrictive intervention is to insure the safety of the person and those in the surrounding area." Review revealed the NCI program provides instruction in the use of non-physical techniques as well as therapeutic holds and transport techniques. Review revealed no documentation of instructions for the manual restraint of a patient on the floor.

Medical record review of Patient #2 revealed the patient was admitted on 01/01/07 for paranoid schizophrenia and died on 02/01/07. Review of the physician's discharge summary dated 02/23/07 revealed, "(Patient's name) was admitted grossly psychotic with a long history of psychiatric care ...The first part of his stay here was characterized by behavioral volatility, including inappropriate and bizarre behavior ...patient was initiated on Zyprexa (an antipsychotic medication) on or about 1/18/07 ...Over the course of the next twelve days, (Patient's name) showed significant improvement. He stopped making so many bizarre statements and became much more engaged with regards to his own personal self-care and personal hygiene. He was still, even on interview, the day before his death, very disorganized and answered many questions with nonsequiturs. However, he was able to sit still, which was markedly improved. He

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was able to respond at least at times appropriately, which was markedly improved and his hygiene showed gross improvement ....Throughout his stay, (Patient's name) really did not have any great physical complaints ... (Patient's name) became abruptly agitated while in the dining room at lunch (on the date of his death). He appeared to be looking for more food, which he had done before and refused redirection. In the past, he typically was redirectable by at least a few staff members and especially lately, had been more redirectable in general. This time, for reasons still unknown to us, he became intensely irate, intensely agitated, and began to throw trashcans around, threatening harm to peers and to staff. Subsequently, he was manually restrained and in the context of that restraint, he apparently suffered some kind of cardiac event and despite provision of CPR on the scene, as well as rapid response of EMS, he expired ..."

Medical record review of documentation by Staff B (a nursing assistant) dated 02/01/07 at 1307 (denoted as "late entry") revealed, "pt. (patient) said 'He was still hungry'; after eating his lunch. Pt was trying to get more food from the ladies that serve food from the window. Pt was redirected, it was effective @ that time. Pt. started going to his table to sit down, he stopped and got five packs of mayo. Pt. said 'I am going to eat them' staff took mayo from the pt.; pt. then walked around, took food out of trashcan and started eating it. Pt. was redirected ineffective staff stopped following pt. Pt. turned trashcan over picked up another trashcan. Mediation was called and ET (Emergency Transmission) button was hit. Staff grabbed pt. then staff lowered pt. to ground pt. tried to kick, bite staff. Pt. was not responding to

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his name. Staff called 2121 Code Blue other staff got first aid kit such as O2 (oxygen) tank and all for CPR."

Medical record review of documentation by Staff L (a nursing assistant) dated 02/01/07 at 1330 (denoted as "late entry") revealed, "I (name of Staff L) walked in, from lunch @ 1200. Everything was ok as usual a few minutes went by. As pt ...stood up and grabbed 4 pack of mayonnaise I and (Staff B) asked pt to give us the mayo pr would not hand them over so we grabbed his hands and took them away. Pt. got up started digging in the trash for mayo or other food. Pt. was very angry. Pt. picked up the trash can and threw it towards staff. A staff member (Staff A), grabbed pt as other staff approached to help. We finally got pt on the ground. Pt. was fighting to get up, pt still angry. After a few minutes pt seemed to have calmed down so we gradually let go but pt wasn't moving or breathing so a staff member called the code while (Staff F) stared CPR. I held the left arm, (Staff I) held right arm, (Staff J) held right leg, (Staff D) held left leg, and (Staff A) on top. (Staff A)'s back facing me could not see pts face or the CNA (nursing assistant) arms or hands."

Medical record review of documentation by Staff J (a nursing assistant) dated 02/01/07 at 1345 (denoted as "late entry") revealed, "...(Staff A) came in and took him down, I seen (Staff A) on top of (Patient's name). I could not see (Patient's name)'s face at all. I did see (Staff I) on (Patient's name)'s right arm holding it. (Staff M) and I were on the right leg. (Staff B) was on the left. (Staff L) had his left arm holding it. (Patient's name) was violently struggling throughout to get up. After several minutes he just stopped. Then a

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nurse asked someone to call 2121 (Code Blue). The medical team came in. Then I was asked to get up and return to my ward."

Medical record review of documentation by Staff M (a registered nurse, RN) dated 02/01/07 at 1300 (denoted as "late entry") revealed, "..."at approximately 1210 pt threw trash can at staff. Pt was placed in MR (manual restraint) resisting staff, I then assisted (Staff A), (Staff L), (Staff D), (Staff I) and (Staff J) with MR. (Staff J) and I were holding pt's L (left) leg. ET was alerted at approximately 1211. (Staff N) RN arrived. Pt was still combative. Approximately 1212 (Staff C) RN and (Staff F) LPN (licensed practical nurse) arrived to assist, at approximately 1215 pt became unresponsive. (Staff N) called code ...."

Medical record review of documentation by Staff I (a nursing assistant) dated 02/01/07 at 1310 (denoted as "late entry") revealed, "...he (Patient #2) grabbed trash can and threw it at staff. At that time we grabbed pt and rolled him to the floor. I had his right arm holding it down, (Staff L) + (Staff D) had his left legg holding it and (Staff J) had his right legg holding it down. (Staff A) was laying across left side of Pt chest with his left arm across his back. We tried letting Pt up to take him to restraint room but Pt start kicking again. Someone asked if we could get an IM (intramuscular injection) and someone said the nurse was bring it. (Staff N) RN said she would give the shot when it came. Shot was not given. Pt went relaxed and (Staff N) said check his eyes and breathing. (Staff C) RN checked and Pt took deep breaths and then stopped. (Staff F) and (Staff C) started CPR and the code team was called ...."

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Medical record review of documentation by Staff C (a RN) dated 02/01/07 at 1330 (denoted as "late entry") revealed, "Upon entering the F1 dining room patient in manual restraints, which was 1210. Patient in manual restraints, duration of five minutes from my arrival. Patient not responding to redirection during manual restraint continued fighting and attempting to bite staff member (Staff A) who was straddling patient. (Staff A) was repeatedly asked if he had weight on him in which his reply was 'no I'm not on him'. (Staff N) attempted to reach patient's doctor for possible PRN (as needed medication) order. Patient continued to fight the manual restraint c (with) no acute physical distress. (Staff N) arrived back @ manual restraint. This writer was to the side of the patient and (Staff N) @ patient's head. At 1215 patient non responsive to verbal or tactile stimulation. (Staff N) and this writer told (Staff A) to get back from patient. No respirations present or pulse present. Staff member called 2121 @ this writer's request ...."

Review of documentation available in the hospital's investigative report by Staff N (a RN) dated 02/01/07 at 1338 revealed, "1212 I walked into dining room p (after) care team was called. Staff had the pt. in the floor. He was screaming and growling at staff. I walked to the door going to the kitchen and called for the operator to page (Physician's Name) at 1213. I walked back staff had stated that the nurses were out side. I walked to the patient's face and became concerned his eyes were closed and his tounge protruded slightly c (with) blue tint. I note at the same time that (Staff A's name) had his R (right) hand on his (pts.) neck Firmly and took his hand told him not to do that and to 'get off his chest' I said twice. Some staff are saying in the

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background 'he will start again'. I said no he's not breathing. 2 or 3 of us said call a code ...." Further review of the hospital's investigative report revealed documentation of a second note by Staff N dated 02/01/07 at 1706 (denoted as "late entry"). Review of the second note made by Staff N revealed, "Heard care team (ET response team) called to (F1) dineing room and responded. Upon arrival 2 RN's and CNA's had pt in NCI Hold. RN's stated pt. was too agitated to move out of the dining room. 1213 called hospital operator. Pt. was growling and kicking fighting staff. Requested operator to call (Physician's name) ASAP to (F1) dining room or this phone. Walked back to pt. assessed his face eyes were closed and tounge was protruded slightly c (with) blueish tint. Instructed staff to stop NCI. Attempted to obtain response, or pulse, and breath sounds. None noted began CPR ..."

Review of documentation available in the hospital's investigative report by Staff A (a nursing assistant) dated 02/01/07 at 1730 revealed, "... (patient) threw the can. At this point to keep other pts and staff safe I wrapped my arms around him from behind. One arm across his right shoulder the other under his left arm and locked my hands in front. I was unable to get him to the floor so I thought if I just hang on till help comes that will at least slow him down. Staff came from all directions trying to grab body parts arms, legs etc. Someone got hold of his head and started pulling down to get him to go to the floor. When I felt the pt starting to go to the floor I quickly loosened my hold to slide around in front of him because he was going to go down on his back. Still with same hold on the floor pt's right side of face was on my right chest. Pt was fighting very hard and at same time was trying so hard to turn his head

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and bite me that his eyes turned blood red and looked as if they were going to pop out. Pt was being held by many staff at this point....when pt had a real hard aggressive attempt to get up and to bite Pt looked as if he passed out so we slowly got off him. At this point RN's checking out Pt and had no response and called Code Blue team."

Medical record review revealed no documented evidence of an "Emergency Restrictive Intervention Progress Note". Further record review revealed no documentation of a physician's order for the manual restraint.

Interview with Staff C on 08/01/07 at 1600 revealed during the manual restraint of Patient #2 on the floor of the dining room on 02/01/07 he and Staff M (the other RN present) "were trying to figure out how to move the patient". Interview revealed the usual process would be to hold the patient down just until he either calmed down and could safely be walked to a safe environment, such as a seclusion or restraint room, or to manually carry the patient (if he is still combative) to a seclusion or restraint room. Interview revealed there are seclusion and restraint rooms readily available on the patient wards and in the treatment mall (the day area). Interview revealed there were no seclusion or restraint rooms in the dining room. Interview revealed in order to carry the patient to the closest seclusion or restraint room, which would have been on Ward 6, they would have had to carry him through 3 sets of doors, 2 of which were locked. Interview revealed carrying the patient to Ward 6 was not feasible because of his large size and the amount of force with which he was fighting the staff. Interview revealed another nurse called the physician to get

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an order for a PRN medication to help calm the patient. Interview revealed the staff continued to manually restrain the patient until he became unresponsive. Interview revealed there was no plan or process in place for the transport of a physically combative patient from the dining room to a seclusion or restraint room.

Nine staff members that witnessed and/or were involved in the manual restraint of Patient #2 in the dining room on 02/01/07 were interviewed on 08/01/07 between 1330 and 1900 (Staff A, Staff B, Staff C, Staff D, Staff E, Staff F, Staff H, Staff I and Staff N). Interview with all 9 staff members revealed the patient was manually restrained on the floor with staff members holding all 4 extremities. All 9 interviews revealed a staff member was positioned on top of the patient diagonally across the patient's chest.

Nine direct patient care staff members (nurses and nursing assistants) were interviewed on 08/01/07 between 1330 and 1900 (Staff A, Staff B, Staff C, Staff D, Staff F, Staff I, Staff K and Staff N). 8 of the 9 staff members interviewed revealed there was no policy or procedure available at the hospital for the manual restraint of a patient on the floor. All of the staff members interviewed revealed the hospital uses NCI techniques for emergency restrictive interventions. Interviews revealed the NCI techniques do not include the use of manual restraints on a patient after the patient is on the floor.

Administrative staff interview on 08/02/07 at 0845 revealed there was no policy or procedure available at the hospital for the manual restraint of a patient on the floor. Interview revealed the

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A 835	Continued From page 32 hospital uses NCI techniques for emergency restrictive interventions. Interview confirmed the NCI techniques do not include the use of manual restraints on a patient after the patient is on the floor. Interview revealed administrative staff had "never thought in terms of we have no practice for this" prior to the incident with Patient #2 on 02/01/07. Interview revealed the process of transporting the patient in his combative state during the manual restraint on 02/01/07 should have been to move him to Ward 6 to a seclusion or restraint room. Interview revealed the staff involved in the manual restraint "couldn't carry him because of his size and the amount of violence". Interview confirmed there was no plan or process for the transport of a physically combative patient from the dining room to a seclusion or restraint room.	A 835		
A 837	482.13(f)(1) PATIENT RIGHTS: RESTRAINT OR SECLUSION Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion before performing any of the actions specified in this paragraph. This STANDARD is not met as evidenced by: Based on hospital policy review, closed medical record reviews, hospital's investigative report review, personnel file reviews and staff interviews the hospital failed to ensure staff were trained in the application of manual restraints of a patient on the floor. The findings include:	A 837		8/10/07

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A 837	Continued From page 33 Review of hospital policy entitled, "Emergency Restrictive Interventions" dated 08/30/06 revealed, "Policy: Isolation time-out, seclusion, manual restraint and/or psychiatric restraint are used only on an emergency basis to terminate a behavior or action in which a patient is in imminent danger of injury to self or others or when substantial property damage is occurring. If possible, verbal or environmental change (i.e. non-physical techniques) is the preferred intervention in the management of behavior. Provision is made for humane, secure, and safe conditions in areas used ....Definitions/Guidelines: Emergency Restrictive Interventions: (Note: Any use must be ordered by a physician and reported on the incident report form.)....Manual Restraint (Man. R) The holding of a patient in an emergency for any length of time in a manner which restricts the patient's freedom of movement. 1. Holding a physically resistive patient in an approved therapeutic hold/carry/walk or other manner that restricts his or her movements constitutes manual restraint for that patient ....This includes therapeutic holds/carries that are approved North Carolina Intervention (NCI) techniques during an emergency, by staff who are NCI-certified. The use of manual restraint for any extended period of time is not sanctioned ..." Review revealed no documentation of instructions for the manual restraint of a patient on the floor. Review of "North Carolina Intervention" manual dated 03/31/03 revealed, "...the immediate goal of the restrictive intervention is to insure the safety of the person and those in the surrounding area." Review revealed the NCI program provides instruction in the use of non-physical techniques as well as therapeutic holds and transport	A 837		

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techniques. Review revealed no documentation of instructions for the manual restraint of a patient on the floor.

Medical record review of Patient #2 revealed the patient was admitted on 01/01/07 for paranoid schizophrenia and died on 02/01/07. Review of the physician's discharge summary dated 02/23/07 revealed, "(Patient's name) was admitted grossly psychotic with a long history of psychiatric care ...The first part of his stay here was characterized by behavioral volatility, including inappropriate and bizarre behavior ...patient was initiated on Zyprexa (an antipsychotic medication) on or about 1/18/07 ...Over the course of the next twelve days, (Patient's name) showed significant improvement. He stopped making so many bizarre statements and became much more engaged with regards to his own personal self-care and personal hygiene. He was still, even on interview, the day before his death, very disorganized and answered many questions with nonsequiturs. However, he was able to sit still, which was markedly improved. He was able to respond at least at times appropriately, which was markedly improved and his hygiene showed gross improvement ....Throughout his stay, (Patient's name) really did not have any great physical complaints ... (Patient's name) became abruptly agitated while in the dining room at lunch (on the date of his death). He appeared to be looking for more food, which he had done before and refused redirection. In the past, he typically was redirectable by at least a few staff members and especially lately, had been more redirectable in general. This time, for reasons still unknown to us, he became intensely irate, intensely agitated, and began to throw trashcans around, threatening

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harm to peers and to staff. Subsequently, he was manually restrained and in the context of that restraint, he apparently suffered some kind of cardiac event and despite provision of CPR on the scene, as well as rapid response of EMS, he expired ..."

Medical record review of documentation by Staff B (a nursing assistant) dated 02/01/07 at 1307 (denoted as "late entry") revealed, "pt. (patient) said 'He was still hungry'; after eating his lunch. Pt was trying to get more food from the ladies that serve food from the window. Pt was redirected, it was effective @ that time. Pt. started going to his table to sit down, he stopped and got five packs of mayo. Pt. said 'I am going to eat them' staff took mayo from the pt.; pt. then walked around, took food out of trashcan and started eating it. Pt. was redirected ineffective staff stopped following pt. Pt. turned trashcan over picked up another trashcan. Mediation was called and ET (Emergency Transmission) button was hit. Staff grabbed pt. then staff lowered pt. to ground pt. tried to kick, bite staff. Pt. was not responding to his name. Staff called 2121 Code Blue other staff got first aid kit such as O2 (oxygen) tank and all for CPR."

Medical record review of documentation by Staff L (a nursing assistant) dated 02/01/07 at 1330 (denoted as "late entry") revealed, "I (name of Staff L) walked in, from lunch @ 1200. Everything was ok as usual a few minutes went by. As pt ...stood up and grabbed 4 pack of mayonnaise I and (Staff B) asked pt to give us the mayo pr would not hand them over so we grabbed his hands and took them away. Pt. got up started digging in the trash for mayo or other food. Pt. was very angry. Pt. picked up the trash

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can and threw it towards staff. A staff member (Staff A), grabbed pt as other staff approached to help. We finally got pt on the ground. Pt. was fighting to get up, pt still angry. After a few minutes pt seemed to have calmed down so we gradually let go but pt wasn't moving or breathing so a staff member called the code while (Staff F) stared CPR. I held the left arm, (Staff I) held right arm, (Staff J) held right leg, (Staff D) held left leg, and (Staff A) on top. (Staff A)'s back facing me could not see pts face or the CNA (nursing assistant) arms or hands."

Medical record review of documentation by Staff J (a nursing assistant) dated 02/01/07 at 1345 (denoted as "late entry") revealed, "...(Staff A) came in and took him down, I seen (Staff A) on top of (Patient's name). I could not see (Patient's name)'s face at all. I did see (Staff I) on (Patient's name)'s right arm holding it. (Staff M) and I were on the right leg. (Staff B) was on the left. (Staff L) had his left arm holding it. (Patient's name) was violently struggling throughout to get up. After several minutes he just stopped. Then a nurse asked someone to call 2121 (Code Blue). The medical team came in. Then I was asked to get up and return to my ward."

Medical record review of documentation by Staff M (a registered nurse, RN) dated 02/01/07 at 1300 (denoted as "late entry") revealed, "..."at approximately 1210 pt threw trash can at staff. Pt was placed in MR (manual restraint) resisting staff, I then assisted (Staff A), (Staff L), (Staff D), (Staff I) and (Staff J) with MR. (Staff J) and I were holding pt's L (left) leg. ET was alerted at approximately 1211. (Staff N) RN arrived. Pt was still combative. Approximately 1212 (Staff C) RN and (Staff F) LPN (licensed practical nurse)

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arrived to assist, at approximately 1215 pt became unresponsive. (Staff N) called code ...."

Medical record review of documentation by Staff I (a nursing assistant) dated 02/01/07 at 1310 (denoted as "late entry") revealed, "...he (Patient #2) grabbed trash can and threw it at staff. At that time we grabbed pt and rolled him to the floor. I had his right arm holding it down, (Staff L) + (Staff D) had his left legg holding it and (Staff J) had his right legg holding it down. (Staff A) was laying across left side of Pt chest with his left arm across his back. We tried letting Pt up to take him to restraint room but Pt start kicking again. Someone asked if we could get an IM (intramuscular injection) and someone said the nurse was bring it. (Staff N) RN said she would give the shot when it came. Shot was not given. Pt went relaxed and (Staff N) said check his eyes and breathing. (Staff C) RN checked and Pt took deep breaths and then stopped. (Staff F) and (Staff C) started CPR and the code team was called ...."

Medical record review of documentation by Staff C (a RN) dated 02/01/07 at 1330 (denoted as "late entry") revealed, "Upon entering the F1 dining room patient in manual restraints, which was 1210. Patient in manual restraints, duration of five minutes from my arrival. Patient not responding to redirection during manual restraint continued fighting and attempting to bite staff member (Staff A) who was straddling patient. (Staff A) was repeatedly asked if he had weight on him in which his reply was 'no I'm not on him'. (Staff N) attempted to reach patient's doctor for possible PRN (as needed medication) order. Patient continued to fight the manual restraint c (with) no acute physical distress. (Staff N) arrived

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back @ manual restraint. This writer was to the side of the patient and (Staff N) @ patient's head. At 1215 patient non responsive to verbal or tactile stimulation. (Staff N) and this writer told (Staff A) to get back from patient. No respirations present or pulse present. Staff member called 2121 @ this writer's request ...."

Review of documentation available in the hospital's investigative report by Staff N (a RN) dated 02/01/07 at 1338 revealed, "1212 I walked into dining room p (after) care team was called. Staff had the pt. in the floor. He was screaming and growling at staff. I walked to the door going to the kitchen and called for the operator to page (Physician's Name) at 1213. I walked back staff had stated that the nurses were out side. I walked to the patient's face and became concerned his eyes were closed and his tounge protruded slightly c (with) blue tint. I note at the same time that (Staff A's name) had his R (right) hand on his (pts.) neck Firmly and took his hand told him not to do that and to 'get off his chest' I said twice. Some staff are saying in the background 'he will start again'. I said no he's not breathing. 2 or 3 of us said call a code ...." Further review of the hospital's investigative report revealed documentation of a second note by Staff N dated 02/01/07 at 1706 (denoted as "late entry"). Review of the second note made by Staff N revealed, "Heard care team (ET response team) called to (F1) dineing room and responded. Upon arrival 2 RN's and CNA's had pt in NCI Hold. RN's stated pt. was too agitated to move out of the dining room. 1213 called hospital operator. Pt. was growling and kicking fighting staff. Requested operator to call (Physician's name) ASAP to (F1) dining room or this phone. Walked back to pt. assessed his face eyes were

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	344002	A. BUILDING _____ B. WING _____	C 08/02/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BROUGHTON HOSP	1000 S STERLING ST MORGANTON, NC 28655

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
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closed and tounge was protruded slightly c (with) blueish tint. Instructed staff to stop NCI. Attempted to obtain response, or pulse, and breath sounds. None noted began CPR ..."

Review of documentation available in the hospital's investigative report by Staff A (a nursing assistant) dated 02/01/07 at 1730 revealed, "... (patient) threw the can. At this point to keep other pts and staff safe I wrapped my arms around him from behind. One arm across his right shoulder the other under his left arm and locked my hands in front. I was unable to get him to the floor so I thought if I just hang on till help comes that will at least slow him down. Staff came from all directions trying to grab body parts arms, legs etc. Someone got hold of his head and started pulling down to get him to go to the floor. When I felt the pt starting to go to the floor I quickly loosened my hold to slide around in front of him because he was going to go down on his back. Still with same hold on the floor pt's right side of face was on my right chest. Pt was fighting very hard and at same time was trying so hard to turn his head and bite me that his eyes turned blood red and looked as if they were going to pop out. Pt was being held by many staff at this point....when pt had a real hard aggressive attempt to get up and to bite Pt looked as if he passed out so we slowly got off him. At this point RN's checking out Pt and had no response and called Code Blue team."

Medical record review revealed no documented evidence of an "Emergency Restrictive Intervention Progress Note". Further record review revealed no documentation of a physician's order for the manual restraint.

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Interview with Staff C on 08/01/07 at 1600 revealed during the manual restraint of Patient #2 on the floor of the dining room on 02/01/07 he and Staff M (the other RN present) "were trying to figure out how to move the patient". Interview revealed the usual process would be to hold the patient down just until he either calmed down and could safely be walked to a safe environment, such as a seclusion or restraint room, or to manually carry the patient (if he is still combative) to a seclusion or restraint room. Interview revealed there are seclusion and restraint rooms readily available on the patient wards and in the treatment mall (the day area). Interview revealed there were no seclusion or restraint rooms in the dining room. Interview revealed in order to carry the patient to the closest seclusion or restraint room, which would have been on Ward 6, they would have had to carry him through 3 sets of doors, 2 of which were locked. Interview revealed carrying the patient to Ward 6 was not feasible because of his large size and the amount of force with which he was fighting the staff. Interview revealed another nurse called the physician to get an order for a PRN medication to help calm the patient. Interview revealed the staff continued to manually restrain the patient until he became unresponsive. Interview revealed there was no plan or process in place for the transport of a physically combative patient from the dining room to a seclusion or restraint room.

Five of 5 personnel files reviewed (of nursing assistants and nurses) involved in the manual restraint of Patient #2 on 02/01/07 revealed no documentation of training for a procedure of manually restraining a patient on the floor.

Nine staff members that witnessed and/or were

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involved in the manual restraint of Patient #2 in the dining room on 02/01/07 were interviewed on 08/01/07 between 1330 and 1900 (Staff A, Staff B, Staff C, Staff D, Staff E, Staff F, Staff H, Staff I and Staff N). Interview with all 9 staff members revealed the patient was manually restrained on the floor with staff members holding all 4 extremities. All 9 interviews revealed a staff member was positioned on top of the patient diagonally across the patient's chest.

Nine direct patient care staff members (nurses and nursing assistants) were interviewed on 08/01/07 between 1330 and 1900 (Staff A, Staff B, Staff C, Staff D, Staff F, Staff I, Staff K and Staff N). 8 of the 9 staff members interviewed revealed there was no policy or procedure available at the hospital for the manual restraint of a patient on the floor. All of the staff members interviewed revealed the hospital uses NCI techniques for emergency restrictive interventions. Interviews revealed the NCI techniques do not include the use of manual restraints on a patient after the patient is on the floor.

Administrative staff interview on 08/02/07 at 0845 revealed there was no policy or procedure available at the hospital for the manual restraint of a patient on the floor. Interview revealed the hospital uses NCI techniques for emergency restrictive interventions. Interview confirmed the NCI techniques do not include the use of manual restraints on a patient after the patient is on the floor. Interview revealed administrative staff had "never thought in terms of we have no practice for this" prior to the incident with Patient #2 on 02/01/07. Interview revealed the process of transporting the patient in his combative state

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A 837	Continued From page 42 during the manual restraint on 02/01/07 should have been to move him to Ward 6 to a seclusion or restraint room. Interview revealed the staff involved in the manual restraint "couldn't carry him because of his size and the amount of violence". Interview confirmed there was no plan or process for the transport of a physically combative patient from the dining room to a seclusion or restraint room. NC00038757	A 837		